

U.S.S.N 09/717,478'  
Anderson *et al.*  
PRELIMINARY AMENDMENT

a photodetector adapted for generating a reflection signal in response to reflected light;

a second fiberoptic bundle optically coupled to the light<sup>NAB</sup> photodetector, and adapted to transmit an amount of reflected light to the photodetector;

an aperture in the reader head body; and

B13  
E1  
a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, wherein: a first portion of the fiberoptic conductor ends comprises fiberoptic conductors of the first fiberoptic bundle; and a second portion of the fiberoptic conductor ends comprises fiberoptic conductors of the second fiberoptic bundle, the plurality of fiberoptic conductor ends being further arranged in a substantially co-planar relationship; and a reader housing comprising:

a housing body; and

a cassette slot adapted to receive a test device.

---

REMARKS

Any fees that may be due in connection with this application throughout its pendency may be charged to Deposit Account No. 50-1213.

The specification is amended to correct typographical errors and to produce grammatical clarity. The amendments to the paragraphs on page 8, lines 13 and 23-24, of the specification correct figure labels and find basis in Figures 1A and 1B. The amendment to the paragraph on page 23, lines 10-16, of the specification corrects figure labels and finds basis in Figures 1A and 1B. The amendment to the paragraph on page 24, lines 14-18, of the specification corrects a figure label and finds basis in Figure 2A. The amendment to the paragraph beginning on page 24, line 29, to page 25, line 18, of the specification corrects a figure label and finds basis in Figures 2A and 2B. The amendment to the paragraph on page 37, lines 12-18, of the specification

**U.S.S.N 09/717,478**  
**Anderson *et al.***  
**PRELIMINARY AMENDMENT**

corrects a figure item label and finds basis on page 39, line 27, of the specification which refers to the test strip as item number "100". The amendment to the paragraph on page 44, lines 19-26, of the specification deletes figure item number "1906" and finds basis on page 45, line 6, of the specification. The amendment to the paragraph on page 46, lines 8-15, of the specification corrects a figure item label and finds basis on page 39, line 27, of the specification which refers to the test strip as item number "100". The amendment to the paragraphs beginning on page 66, line 10, to page 67, line 6, of the specification corrects a figure label and corrects figure item labels. The amendment finds basis in Figures 1A and 1B and finds basis on page 65, line 13, of the specification which refers to the absorbent pad as item number "110". The amendment to the paragraph on page 67, lines 7-11, of the specification corrects figure item labels and adds the label "320" distinguish the lower member of the housing from the sample application port "304". The amendment finds basis in Figure 3.

The paragraphs on page 29, lines 20-28, and on page 64, line 28, to page 65, line 13, were corrected by a preliminary amendment dated February 28, 2001. The instant amendment further seeks to amend these paragraphs by correcting figure labels. This correction finds basis in Figures 1A and 1B.

The corrections to the drawings correct minor typographical errors and find basis in the specification. In particular, the amendment to Figures 2B and 3 label the upper and lower housing members as "302" and "320", respectively, to distinguish them from the sample application port "304". The amendment finds basis on page 67, lines 8-9, of the specification. The amendment to Figure 19 corrects a figure item label and finds basis on page 40, line 5, of the specification which refers to the aperture as item number "1108". The amendment to Figures 21-23 corrects a figure item label and finds basis on page 42, line 27, of the specification which refers to the aperture as item number "1108".

**U.S.S.N 09/717,478**  
**Anderson *et al.***  
**PRELIMINARY AMENDMENT**

The amendment to claim 5 corrects a typographical error and produces grammatical clarity. No new matter has been added.

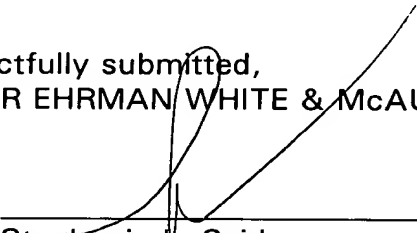
Included as an attachment is a marked-up version of the specification paragraphs that are being amended, per 37 CFR §1.121.

\* \* \*

Entry of this amendment and examination of the application are respectfully requested.

Respectfully submitted,  
HELLER EHRMAN WHITE & McAULIFFE LLP

By:

  
Stephanie L. Seidman  
Registration No. 33,779

Attorney Docket No. 24727-813C  
**Address all correspondence to:**  
Stephanie L. Seidman, Esq.  
HELLER EHRMAN WHITE & McAULIFFE  
4350 La Jolla Village Drive  
San Diego, California 92122-1246  
Telephone: (858) 450-8400  
Facsimile: (858) 587-5360  
email:sseidman@HEWM.com



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Anderson *et al.*  
Serial No.: 09/717,478  
Filed: November 20, 2000  
For: *POINT OF CARE DIAGNOSTIC  
SYSTEMS*  
Art Unit: 3736  
Examiner: Unassigned

**ATTACHMENT TO THE PRELIMINARY AMENDMENT  
MARKED UP PARAGRAPHS AND CLAIMS (37 CFR §1.121)**

**IN THE SPECIFICATION:**

Please amend the specification as follows:

**Please amend the paragraph on page 8, line 13, as follows:**

FIG. 1B is a side view of the assay test strip of FIG. [1]1A;

**Please amend the paragraph on page 8, lines 23-24, as follows:**

FIG. 4 is a top view of an exemplary housing assembly for the assay test strip of [FIG. 1]FIGs. 1A and 1B;

**Please amend the paragraph on page 23, lines 10-16, as follows:**

A preferred embodiment is an immunoassay test strip that includes a membrane system that defines a liquid flow pathway. An exemplary immunoassay test strip provided herein is shown in [FIG. 1]FIGs. 1A and 1B. The test strip is described in detail in EXAMPLE 1. This test strip is provided for purposes of exemplification of the methods and systems provided herein and is not intended to limit the application to immunoassay test strip devices.

**U.S.S.N 09/717,478**

**Anderson *et al.***

**PRELIMINARY AMENDMENT ATTACHMENT**

**Please amend the paragraph on page 24, lines 14-18, as follows:**

The test strip optionally may be contained within a housing for insertion into the reflectance reader. The housing may be made of plastic or other inert material that does not interfere with the assay procedure. An exemplary assay device, including a test strip and housing assembly is shown in FIGs. [2-5]2A-5.

**Please amend the paragraph beginning on page 24, line 29, through page 25, line 18, as follows:**

In a particular embodiment, Code 39 is used. An example bar code is shown in FIG. 25. The bar code is made up of 11 alphanumeric characters, including 2 alphabetic and 9 numeric characters. The first and last characters are asterisks (\*), as is standard in the Code 39 system. The lot number is stored as 1 alpha and 4 numeric codes so that product complaints or questions can be traced to a particular lot number. In the exemplified embodiment, the first character represents the month of production, the second is a digit representing the year of production and the last three are an index value indicating the lot number. Thus, the lot number "A8001" represents the first device in a lot produced in January, 1998. The next two characters ("01") represent the identity of the analyte as 2 numerics (00-99). This permits the use of up to 100 different analytes with the system. The reflectance intensity value (00-99) is stored as the next two numeric characters ("01"). The intensity value sets the reference threshold for which controls and patient samples can be compared. This eliminates the need to run liquid reference samples on a daily basis. [FIGs. 2 and 3]FIGs. 2A, 2B, and 3 depict assay devices that optionally include bar codes, **216** and **316**, respectively. Finally, the cassette expiration date is stored as 1 alpha and 1 numeric code to prevent the use of expired devices. In the example given, an expiration code of "A9" represents an expiration date of January, 1999.

**PRELIMINARY AMENDMENT ATTACHMENT**

**Please amend the paragraph on page 29, lines 20-28, as follows:**

A volume of the test sample is then delivered to the test strip [(FIG. 1)](FIGs. 1A and 1B) using any known means for transporting a biological sample, for example, a standard plastic pipet. Any analyte in the sample binds to the labeled antibody, and the resulting complex migrates along the test strip. Alternatively, the sample may be pre-mixed with the labeled conjugate prior to applying the mixture to the test strip. When the labeled antibody-analyte complex encounters a detection zone of the test strip, the immobilized antibody therein binds the complex to form a sandwich complex, thereby forming a colored stripe.

**Please amend the paragraph on page 37, lines 12-18, as follows:**

As can be seen, the actuator arm **1004**, the actuator spring **1002**, the stepper motor **802**, the reader head **706**, the reader head mounting bracket **1204**, and mechanisms used for supporting and scanning the reader head **706** are designed so that the test strip **[214] 100** in the device **200** is positioned within 0.010 inches of the aperture **1108** of the reader head. Any design suitable to effect such can be employed with the present embodiment.

**Please amend the paragraph on page 44, lines 19-26, as follows:**

At the fiberoptic conductor ends **1902, 1904, 1906**, each fiberoptic fiber (or conductor) has a longitudinal axis that is normal to the plane at the upper surface of the bar code or test strip. As a result, light emitted from the fiberoptic conductor ends **[1902, 1904, 1906] 1902 and 1904** is directed in a direction substantially normal to this surface plane. The fiberoptic fibers in each of the three groups are arranged along with fiberoptic fibers from the remaining groups in a sigmoidal (or "S"-like) pattern with three columns of thirteen fibers each.

PRELIMINARY AMENDMENT ATTACHMENT

Please amend the paragraph on page 46, lines 8-15, as follows:

After being positioned above the housing, the reader head 706 is moved (scanned) across the bar code and/or test strip by the stepper motor under the control of the control circuit to allow the reader head 706 to scan the exposed surface of the bar code and/or assay test strip (including the detection and control zones through the test window 214 in the immunoassay device). As stated above, in a preferred embodiment, the distance between reader head 706 and the bar code or assay test strip [200] 100 is approximately 0.010".

Please amend the paragraph beginning on page 64, line 28, through page 65, line 13, as follows:

The test strip 100 includes a membrane system including three components: a porous or bibulous member 102; a conjugate pad 108; and an absorbent pad 110. The membrane system may be mounted on a substrate or backing 112, with the conjugate pad 108 and the absorbent pad 110 slightly overlapping the porous or bibulous member 102, which is interposed thereinbetween. As can be seen in [Figure 1]Figures 1A and 1B, the conjugate pad 108 overlaps the porous or bibulous member 102 so that a fluid sample placed onto the conjugate pad 108 is communicated from the conjugate pad 108 to the porous or bibulous member 102. Similarly, the absorbent pad 110 overlaps with the porous or bibulous member 102 so that fluid samples introduced into the porous or bibulous member 102 from the conjugate pad 108 can then be transmitted to the absorbent pad 110. Thus, the conjugate pad 108, the absorbent pad 110 and the porous or bibulous member 102 are all in fluid communication with one another, making any fluid sample placed on the conjugate pad 108 able to propagate through the conjugate pad 108 to the porous or bibulous member 102 and then to the absorbent pad 110.

PRELIMINARY AMENDMENT ATTACHMENT

Please amend the paragraphs beginning on page 66, line 10, through page 67, line 6, as follows:

The membrane system may also include an absorbent pad [112] 110, which is also in fluid communication with the porous or bibulous member, and which serves to draw liquid continuously through the device. The absorbent strip may be made of a material such as cellulose paper or other material known to those of skill in the art.

Referring to FIG. 2A, which depicts an exemplary immunoassay device, including a test strip and housing assembly 200, the housing 202 generally surrounds the test strip 100 ([FIG. 1] FIGs. 1A and 1B) and includes an opening through which test sample is applied 204, as well as an aperture above the detection and control zones 206 that permits measurement of the amount of label by the reader, which is correlated with the amount of analyte in the test sample. The housing 202 includes at its upper surface 208 a fattened end 210, used for gripping the housing 202, an application window 204 (or sample window) through which a sample is applied to a conjugate pad 108 of an immunoassay test strip within the housing 202. The housing 202 also includes a test window 214 through which the test result of the immunoassay is viewed. In accordance with the embodiments shown, no window material is mounted within the test window 214 (or the sample window 212). Thus, an optical path from outside the housing 202 through the test window 214 to the immunoassay test strip is unobscured by even a transparent material. Other alternative embodiments may include an optically transparent material (transparent at wavelengths emitted by light emitted from devices described herein), however, such is not preferred. Also, as shown in FIG. 2A and FIG. 2B, the housing may include a symbology, exemplified as a bar code 216 or 316 that can be read by the reader or a separate reading device and associated with identifying information pertaining to the particular device and/or test run or other information.

PRELIMINARY AMENDMENT ATTACHMENT

Please amend the paragraph on page 67, lines 7-11, as follows:

An alternative embodiment of the test device is shown in FIG. 2B. The components of device are shown in FIG. 3 and include the upper and lower members **302** and **[304] 320** of the housing and the test strip **100**. Also shown are the sample application port **[306] 304**, test window **[308] 314**, and the optionally included bar code **316**.

**IN THE CLAIMS:**

Please amend claim 5 as follows:

5. (Amended Twice) The method of claim 1, wherein the reader is a reflectance reader, comprising:

a reader head comprising:

a reader head body;

a light emitting diode;

a first fiberoptic bundle optically coupled to the light emitting diode, and adapted to [transmitting]transmit light from the light emitting diode;

a photodetector adapted for generating a reflection signal in response to reflected light;

a second fiberoptic bundle optically coupled to the light photodetector, and adapted to transmit an amount of reflected light to the photodetector;

an aperture in the reader head body; and

a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, wherein: a first portion of the fiberoptic conductor ends comprises fiberoptic conductors of the first fiberoptic bundle; and a second portion of the fiberoptic conductor ends comprises fiberoptic conductors of the second fiberoptic bundle, the plurality of fiberoptic conductor ends being further arranged in a substantially co-planar relationship; and a reader housing comprising:

a housing body; and

U.S.S.N 09/717,478

Anderson *et al.*

**PRELIMINARY AMENDMENT ATTACHMENT**

a cassette slot adapted to receive a test device.